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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/640,366	DEGOULD, MICHAEL D.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-14,16-20 and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-14,16-20 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment filed July 17, 2007. All rejections have been withdrawn unless stated below. Claims 1-24 are rejected.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)

1) Claims 12-13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Berggren et al. (US 5,620,700).

Berggren et al. disclose injectable drug delivery systems comprising a polymeric matrix material that is less or non-flowable at or below body temperature and a flowable polymer at a physiologically compatible elevated temperature, which ranges from 38°C to 75°C (col. 4, lines 65-67). The compositions are delivered by a syringe to the periodontal pocket. When the compositions are heated, they are flowable thereby meeting the limitation of the instant claims (col. 5, lines 35-40). The polymers include cross-linked collagens and cross-linked gelatins (col. 6, lines 34-38). The collagens and gelatins are cross-linked therefore it may be concluded they were made with a cross-linking agent. The compositions are used to fulfill the need for a device which can be more quickly and easily placed in a tissue pocket, and will conform more exactly to the

size and shape of each individual pocket for the release of a beneficial agent in order to treat a disease condition (col. 5, lines 59-65). The intended use of the wound dressing compositions carries no weight in determining the patentability of the instant claims because the compositions disclosed by the reference are substantially the same, comprising a cross-linked collagen or gelatin, as the compositions disclosed and claimed by the Applicant. Accordingly, in regards to the intended use, one would have reasonably expected that the compositions of the reference have substantially the same properties, treating alveolar osteitis and pain following tooth extraction of jaw cyst removal, as the applicant's compositions, since the compositions of the reference and the compositions of the instant claims are substantially the same. The reference anticipates insofar as it discloses a syringe comprising a flowable, moldable biocompatible gel prepared by a collagen derivative a non-cytotoxic cross-linking agent.

2) Claims 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Smestad et al. (US 4,582,640).

Smestad et al. disclose injectable cross-linked collagen compositions. The collagen includes atelopeptide collagen. Syringes are used to deliver the collagen to the desired area. The compositions are gel suspensions. The cross-linking agents are aldehydes (see Abstract). The intended use of the wound dressing compositions carries no weight in determining the patentability of the instant claims because the compositions disclosed by the reference are substantially the same, comprising atelocollagen and a cross-linking agent, as the compositions disclosed and claimed by

the Applicant. Accordingly, in regards to the intended use, one would have reasonably expected that the compositions of the reference have substantially the same properties, treating alveolar osteitis and pain following tooth extraction of jaw cyst removal, as the applicant's compositions, since the compositions of the reference and the compositions of the instant claims are substantially the same. The reference anticipates insofar as it discloses a syringe comprising a flowable, moldable biocompatible gel prepared by a collagen derivative a non-cytotoxic cross-linking agent.

Claim Rejections - 35 USC § 103

1) Claims 1-2, 4-6, 8-9,16, 19, 25-26 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US 5,002,769) in view of Berggren et al. (US 5,620,700).

Friedman discloses compositions for sustained release of chlorhexidine to treat conditions such as pain and dry socket. The compositions comprise a cross-linked protein such as gelatin and collagen (col. 4, lines 43-46). Cross-linking agents may be di, tri or tetra valent ions such as aluminum, chromium, titanium or zirconium ions (col. 5, lines 25-30). The compositions are used as an adjunct to surgery to treat post-surgical infection (col. 11, lines 3-7). The compositions are also used to treat the problem of "dry socket" after tooth extraction (col. 10, lines 55-59). The compositions are gel compositions that are dried to make a film. These films are placed in the desired area. The reference differs from the instant claims insofar as it does not disclose the compositions are flowable gels when enclosed into a cavity after tooth extraction.

The secondary reference, Berggren et al., is discussed above. One of the drugs that are deliverable by this system is chlorhexidine (col. 8, line 60). The reference differs from the instant claims insofar as it does not disclose the oral condition the compositions are used to treat is alveolar osteitis.

It would have been obvious to one of ordinary skill in the art to have used the flowable gel compositions to treat the periodontal condition of the primary reference "dry socket" motivated by the desire to use a composition or device which can be more quickly and easily placed in a tissue pocket, and will conform more exactly to the size and shape of each individual pocket for the release of a beneficial agent in order to treat a disease condition, as disclosed by the secondary reference.

2) Claim 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US 5,002,769) in view of Berggren et al. (US 5,620,700) as applied to claims 1-2, 4-6 and 8-9 in further view of Miller et al. (US 6,509,031).

The primary and secondary references are discussed above. The references differ from the instant claims insofar as it does not disclose the collagen or gelatin was cross-linked by hydrogen peroxide.

Miller et al. disclose collagen gel compositions used as a wound sealant. The collagen compositions may be used for dental compositions and injected into the desired sites where the compositions form the cross-linked gels in situ (col. 2, lines 16-20). When peroxide is used in the compositions, inhibition of bacterial growth is achieved. These compositions also are less likely to cause an inflammatory reaction

than glutaraldehyde cross-linked collagen (col. 5, lines 51-53). The reference differs from the instant claim insofar as it does not disclose the compositions are used for treatment of alveolar osteitis and pain and that the compositions are flowable gels enclosed in an oral cavity.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used hydrogen peroxide as the cross-linking agent in the method of the combined primary and secondary references motivated by the desire to use a cross-linking agent that was less likely to cause an inflammatory reaction than glutaraldehyde and for its function as a cross-linking agent, as taught by the tertiary reference and supported by cited precedent.

3) Claims 3, 10, 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US 5,002,769) in view of Berggren et al. (US 5,620,700) as applied to claims 1-2, 4-6, 8-9,16, 19, 25-26 and 28-29 in further view of Higashi et al. (US 4,906,670).

The primary and secondary references are discussed above. The references differ from the instant claims insofar as it does not disclose the atelocollagen as the collagen used in the compositions.

Higashi et al. disclose pharmaceutical compositions for treatment of periodontal disease. The compositions comprise atelocollagen and a cross-linking agent (col.3, lines 40-42). The compositions may be in the form of a gel, ointment or film (col. 3, lines 23-25). In regards to the compositions being syringable, since the compositions may be in the form of a gel or ointment they may be extruded (see claim 1) from a source such as a syringe. Atelocollagen exhibits no antigenicity since the telopeptide chain responsible for immuno-activity has been removed; has a good affinity to vital tissues; stimulates bio-synthesis or metabolism of collagen; has an action to accelerate the healing of wounded connective tissues and formation of epitherial tissues; and is capable of being easily modified by, for example, formation of cross linkage by the use of chemical agents such as glutaraldehyde, or irradiation of ultraviolet light or rays, whereby the release rate of active ingredients can be easily controlled (col. 3, lines 43-56). The reference differs from the instant claims insofar as it does not disclose the compositions are flowable gels delivered by a syringe to treat alveolar osteitis and pain.

It would have been obvious to one of ordinary skill in the art to have used atelocollagen as the collagen in the method of the combined primary and secondary references motivated by the desire to use a collagen that exhibits no antigenicity; has a good affinity to vital tissues; stimulates bio-synthesis or metabolism of collagen; has an action to accelerate the healing of wounded connective tissues and formation of

epitherial tissues; and is capable of being easily modified, as taught by the tertiary reference and supported by *Sinclair & Carroll Co. v. Interchemical Corp.*, *In re Linder,* and *In re Dial*, cited above.

Claims 1-10, 12-14, 16-20 and 25-29 are rejected.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
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